



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016- N-0001]

Diabetes Outcome Measures Beyond Hemoglobin A1c: CDER Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER), is sponsoring a public workshop entitled "Diabetes Outcome Measures Beyond Hemoglobin A1c (HbA1c)." The purpose of this public workshop is to have a forum for dialogue with the public, patients, patient advocacy groups and industry to gain greater appreciation on the extent to which the current regulatory paradigm for antidiabetic drug therapies addresses the needs of patients with diabetes and to identify additional outcomes, beyond HbA1c, that are of direct relevance and importance to patients living with the disease.

DATES: The public workshop will be held on August 29, 2016, from 9 a.m. to 5 p.m.

ADDRESSES: The public workshop will be held at FDA's White Oak campus, 10903 New Hampshire Ave., Building 31 (The Great Room B, and C), Silver Spring, MD 20993. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to

<http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

FOR FURTHER INFORMATION CONTACT: Francis Kalush, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, DIABHbA1c-CDER@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA is announcing a public workshop entitled “Diabetes Outcome Measures Beyond Hemoglobin A1c.” This public workshop is intended to gain greater appreciation on the extent to which the current regulatory paradigm for drugs to treat diabetes addresses the needs of patients with diabetes, to identify what the most urgent unmet patient needs are and to identify measures beyond HbA1c that would reliably capture outcomes important to the health or quality of life of patients living with diabetes. The ultimate purpose of identifying and qualifying these outcomes for regulatory purposes would be to continue to support the development of novel therapies that directly address the needs of patients living with the disease. There will be an opportunity for questions and answers following each presentation.

Registration: There is no registration fee to attend the public workshop. Early registration is recommended because seating is limited, and registration will be on a first-come, first-served basis. There will be no onsite registration. Persons interested in attending this workshop must register online at <http://www.fda.gov/Drugs/NewsEvents/ucm499281.htm> by July 29, 2016. For those without Internet access, please contact Francis Kalush (see FOR FURTHER INFORMATION CONTACT) to register.

If you need special accommodations due to a disability, please contact Francis Kalush (see FOR FURTHER INFORMATION CONTACT) at least 7 days in advance.

Transcripts: A transcript of the workshop will be available for review at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and on the Internet at <http://www.regulations.gov> approximately 30 days

after the workshop. Transcripts will also be available in either hard copy or on CD-ROM, after submission of a Freedom of Information request. The Freedom of Information office address is available on the Agency's Web site at <http://www.fda.gov>.

Dated: May 13, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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